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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,427	01/12/2004	Lee Bolduc	203-2626 DIV CON VIII (24)	9695
7590 Mark Farber, Esq. U.S. Surgical, A Division of Tyco Healthcare Group, LP 150 Glover Avenue Norwalk, CT 06856			EXAMINER YABUT, DIANE D	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 09/28/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/755,427	<b>Applicant(s)</b> BOLDUC ET AL.	
	<b>Examiner</b> DIANE YABUT	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/10/2009 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 6-9, 11, 14, 16 and 19-24 are rejected under 35 U.S.C. 102(b) as being anticipated by **Noiles et al.** (U.S. Patent No. **Re 28,932**).

Noiles et al. disclose an applicator with a disposable distal portion having an elongate outer tube **26**, a connecting end and a terminal end (Figure 6), a reusable proximal portion having a handle **12** and an actuator **28**, the proximal portion being releasably attached to the connecting end of the distal portion (Figures 1 and 6), and a rotator **218** (directly coupled to and rotated by element **38**) cooperating with the

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actuator, the rotator including a longitudinal groove **220** (Figure 19), the groove configured to receive a plurality of fasteners **208**, wherein the rotator resides within and extends substantially the length of the outer tube such that actuation of the actuator rotates and translates the fasteners relative to the outer tube while the rotator remains longitudinally stationary with respect to the outer tube (Figures 1, 19-20; col. 11, lines 34-57).

A nose piece **204** is attached to the terminal end, the nose piece having structure projecting perpendicularly toward a longitudinal axis of the outer tube and adapted to engage the plurality of fasteners (Figure 21).

The actuator includes a lever **28** having a first end and a second end, the lever pivotally attached about a midpoint to the handle, the first end of the lever for gripping by hand, a lead screw **32** rotatably attached to an interior of the handle, a nut driver **70**, the second end **50** of the lever pivotally attached to the nut driver, the nut driver for traveling along the lead screw, thereby turning the lead screw, and the lead screw attached to the rotator so that as the lever is depressed by hand the nut driver will travel along the lead screw towards the rotator thereby turning the rotator **38/218** in the process, and (Figures 1-3). The lever has a midsection extension **44** (Figure 1).

A means or ratchet mechanism **32/34/94** is disclosed for the lead screw **32** to releasably engage the rotator **38/218** so that as the lever **28** is depressed by hand, the nut driver **70** will travel along the lead screw **32** toward the rotator thereby turning the rotator in the process and so that when the lever is returned to its undepressed position the lead screw **32** will rotate the reverse ("counter-clockwise") direction and

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(positionably) independently of the rotator which remains (longitudinally) stationary (Figures 1-4; col. 7, lines 29-64).

The rotator **218** is configured to eject each fastener and the longitudinal groove is configured to releasably receive the portion of each one of the plurality of fasteners, wherein the longitudinal groove is adapted to slidably receive the portion **210** of each one of the plurality of fasteners, wherein the fasteners surround the rotator, the longitudinal groove being formed on an outer surface of the rotator and is substantially parallel to a longitudinal axis of the rotator (since the helical threading of the groove **220** has a length or has portions that are parallel to the longitudinal axis). See Figures 19-22.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Noiles et al.** (U.S. Patent No. **Re 28,932**) in view of **Smith et al.** (U.S. Patent No. **4,596,350**).

Noiles et al. disclose the claimed device, except for a lock/clip indicator for engaging a plurality of fasteners which is configured to prevent actuation of the actuator

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upon discharge of the plurality of fasteners from the applicator, and a load spring for applying longitudinal forces against the lock/clip indicator.

Smith et al. teach a lock/clip indicator **51** for engaging a plurality of fasteners which is configured to prevent actuation of the actuator upon discharge of the plurality of fasteners from the applicator, and a load spring **20** for applying longitudinal forces against the lock/clip indicator (col. 9, lines 35-52). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a lock/clip indicator and load spring, as taught by Smith et al., to Noiles et al. since it was known in the art that lock/clip indicators with spring mechanisms prevent undesirable forward advancement of fasteners.

6. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Noiles et al.** (U.S. Patent No. **Re 28,932**) in view of **Miller** (U.S. Patent No. **4,628,943**).

Noiles et al. disclose the claimed device, except for the terminal end having a thread form with an interlock spring.

Miller teaches a thread form **62** contained in an interior of a terminal end **66** adapted to engage a plurality of fasteners, such as **36**, wherein the thread form is an interlock spring **60** (having a helical passageway **62**) fixedly retained in the interior of the terminal end, wherein the spring provides an actuating force (Figure 3). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the terminal end of Noiles et al. with a thread form, as taught by Miller, in order to introduce

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helical coil-shaped fasteners instead of the T-shaped fasteners **208** in Noiles et al, since coil fasteners are old and well known in the art.

7. Claims 10, 15, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Noiles et al.** (U.S. Patent No. **Re 28,932**).

Noiles et al. disclose the claimed device, except for the lead screw being a high helix lead screw instead of a ratchet **32**. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a high helix lead screw for the lead screw/ratchet in Noiles et al. since it was old and known in the art that high helix angle thread screws are high efficiency using low rotational speeds.

In addition, Noiles et al. do not expressly disclose the fasteners being formed from an absorbable material. However, it would have been obvious to one of ordinary skill in the art to provide absorbable material to the fasteners since it was old and well known in the art that absorbable staples facilitate wound closure and healing of tissue.

8. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Noiles et al.** (U.S. Patent No. **Re 28,932**) in view of **Pratt et al.** (U.S. Patent No. **5,487,500**).

Noiles et al. disclose the claimed device, except for gear teeth formed within the interior of the handle, a spring loaded pawl pivotally attached to the midsection extension and adapted to engage gear teeth.

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Pratt et al. teach gear teeth **48** formed within the interior of a handle, a spring loaded pawl **40** (by spring **42**) pivotally attached to the midsection and adapted to engage the gear teeth (Figures 2a-3). It would have been obvious to one of ordinary skill in the art at the time of invention to provide engaging gear teeth and a pawl, as taught by Pratt et al., to Noiles et al. in order to lock the handle in a desirable position to prevent over advancement of the fasteners (see abstract).

9. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Noiles et al.** (U.S. Patent No. **Re 28,932**) in view of **Knodel et al.** (U.S. Patent No. **5,487,500**).

Noiles et al. disclose the claimed device, except for formed in the mid-section extension are a plurality of teeth and a latch pawl cooperating with the teeth to prohibit the lever from backstroking until it has completely depressed.

Knodel et al. teach a mid-section having a plurality of teeth that cooperate with a latch pawl (Figure 6). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a plurality of teeth on the mid-section extension of the lever of Noiles et al. and a corresponding latch pawl, as taught by Knodel et al., to Noiles et al. in order to prevent inadvertent delivery of fasteners.

### ***Response to Arguments***

10. Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.



***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3734